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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,817	11/08/2000	Jose Remacle	VANM160.001A	2892

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
SISSON, BRADLEY L	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 09/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Acti n Summary	Applicati n No.	Applicant(s)	
	09/582,817	JOSE REMACLE	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P ri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *30-41,43-47,49 and 50* is/are pending in the application.

4a) Of the above claim(s) *32,33,49 and 50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30,31 and 34-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. In response to applicant's remarks regarding the election of nucleotide sequences, found at page 3 of the response of 14 January 2003, claim 31 has been rejoined and is hereby considered on the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 30, 31, and 34-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision of *Vas-Cath Inc. v. Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

> This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 USC 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

4. For convenience, claim 30, the sole independent claim, is reproduced below.

> Claim 30 (Amended). A method for the detection of a target molecule present in a sample, comprising the steps of:
> allowing binding between said target molecule and a capture molecule fixed upon a side of the surface of a solid support, said solid support comprising a disc, wherein said binding results in a detectable signal, and wherein said disc comprises registered data located on areas separated from the areas where the signal is generated;
> detecting said signal, wherein said signal is not obtained through cleavage of the capture molecule, and
> reading the registered information and reading the signal resulting from the binding between said target molecule and said capture molecule, said readings being done by two different reading devices.

5. Acknowledgement is made of where applicant has deleted certain embodiments from the claims; see page 5, first paragraph of the response of 14 January 2003, hereinafter the response. While the claims may not explicitly recite such embodiments, the claims, for purposes of examination, have been interpreted as encompassing detection of nucleic acids on a disc where the detection takes place in groves, and virtually any detectable signal is employed (claims 30, 31, and 43-47).

6. Said claims have also been interpreted as encompassing performance of any part of the assay, including fluid flow, binding, manipulation of reagents, etc., while at the same time having the disc rotate at any speed such that information stored in groves (e.g., the binary information of claim 45) is read and any signal so produced in the course of the assay is also detected and interpreted (claim 43).

7. Said claims have also been interpreted as encompassing a disc where reagents, binding areas and detection areas are located within groves.

8. A review of the specification finds that only certain types or sizes of discs are adequately described. Page 7 states that the discs are 1.2 mm thick and 12 cm in diameter. Also, page 12 of

the disclosure provides added description of the disc to be used in the claimed method. As seen therein, the disc can range from 5 cm to 30 cm and varies in thickness from 1mm to 2 mm. The specification has not been found to provide an adequate written description of alternative sizes/dimensions for discs to be sued in the claimed method. Accordingly, applicant is urged to consider narrowing the claims to those embodiments adequately described.

9. As noted above, the claimed method has been interpreted as encompassing use of a disc where the reagents, binding, and detection all take place in grooved areas, as can be binary data. Page 18 of the disclosure, however, cautions the skilled artisan not to place capture moieties in grooved areas so as to avoid false positive signals. Page 25, second paragraph, discloses the binary information being located in "pits, preferably in the grove adjacent to the non-cleavable capture molecule." Such teachings do not reasonably suggest that applicant has possession of a method whereby capture moieties and the assay in general is conducted in grooves located on or in a disc of any dimension.

10. The disclosure has been found to contain the following examples:

- Example 1, pages 26-28, "Detection of DNA on CD
  - Amination of polycarbonate of CD (page 26)
  - Fixation of capture probes on aminated CDs (page 27)
  - Hybridization of CMV biotinylated DNA on CDs (page 27)
  - Detection of hybridized DNA (page 28)
- Example 2, page 28, Detection of DNA on CD with maser detection
- Example 3, pages 28-30, Detection of protein on CD by light absorption
  - Carboxylation of CD (page 29)

- Fixation of antibodies on CDs (page 29)
- Detection of bovine serum albumin by ELISA technique on CD (pages 29-30)

o Example 4, page 30, Detection of proteins on CD with laser detection

o Example 5, pages 30-31, Magnetic detection of DNA or protein on CD

11. Of the above-identified examples, only examples 1, 2, and 5 related to the elected invention. It is noted that in the case of Example 1, a picture of the disc was taken for review and that this picture was taken post color development. It would appear that the only "device" used to detect the signal (claim 30, third indent) was artisan's eyes.

12. As presently worded, the claimed method fairly encompasses direct and simultaneous reading of information written on the disc and signals produced from precipitate/colloidal accumulation on the capture probe. A review of the specification fails to find where such direct readings have been performed and are reproducible. In Example 2, it is noted that streptavidin-colloidal gold was used to detect biotinylated DNA spotted on the CD. Subsequent to the binding of streptavidin-colloidal gold to the biotinylated probe, "[t]he CD was further incubated 30 min in a solution made of equal volume of Solution A and B from Silver enhancement kit (Sigma, St. Louis, USA) in order to have silver precipitate where positive hybridization occurred. This CD was recovered with a gold layer to allow a laser CD player to read information written on the CD and to read the interference due to silver precipitate (Fig. 2 and 3)." So while the specification does set forth means for reading information on a disc and for detecting signal (silver precipitate), such is of but a single embodiment and then requires additional steps. The specification does not set forth in sufficient detail the claimed method of detecting precipitates or the fixation of but one molecule (claims 30 and 39-41) to the capture molecules. Further, the

specification does not set forth in sufficient detail any assay format where the reagents are allowed to bind to one another while the disc is spinning, wherein said spinning takes place at virtually any speed and wherein the reagents are on any exposed surface of the disc. While applicant has asserted that the claimed invention can be practiced in such a manner, a review of the disclosure fails to find adequate written description of such a methodology such that it reasonably suggest that applicant was in possession of said method at the time of filing. Applicant is urged to consider narrowing the claims' scope to those embodiments adequately described by the disclosure.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claims 30, 31, 35-47 rejected under 35 U.S.C. 103(a) as being unpatentable over Virtanen (US Patent 6,030,581) in view of Rushbrooke et al. (US Patent 6,263,095 B1).

16. Virtanen discloses a method of detecting nucleic acid wherein said nucleic acids are captured by a capture probe that is immobilized to a surface of a disc, wherein said disc is a CD, DVD.

17. Virtanen, column 5, discloses the analyte (applicant's elected species of nucleic acid) binding to predetermined locations on the disk. Said disc comprises at least two sections, one for the assay and one where information is written and is separately read be a reader.

18. Virtanen does not disclose detection of the target molecule through signals such as fluorescence or precipitate.

19. Rushbrooke et al., teach at length of using imaging means to detect the presence of nucleic acids through detection of bound label that emits light; see column 4, penultimate paragraph. Column 8 explicitly addresses use of multiple labels in a single assay. Column 10, lists a variety of assay that can be conducted. Such assays include "high density arrays of oligonucleotides, peptides, DNA, proteins, carbohydrates or polysaccharides." Column 12 discloses use of fluorescent labels.

20. Column 11 provides advantages to the system.

21. The aspect of label moieties in solution binding to a target molecules located on a solid support is considered to meet the limitation of there being a precipitate upon the surface of the disc (claim 39).

22. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the method of detection disclosed by Rushbrooke et al., with that of Virtanen as the use fluorescent labels and detection of same via a CCD reader would provide for improved accuracy and ease of operation. In view of the detailed disclosure provided by

Rushbrooke et al., said ordinary artisan would have had a most reasonably expectation of success.

Conclusion

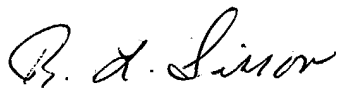
23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

24. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is 703-308-3978. The examiner can normally be reached on Monday through Thursday from 6:30 AM to 5 PM.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

27. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
September 20, 2003